HUBERT H. HUMPHREY, III
ATTORNEY GENERAL

STATE OF MINNESOTA

OFFICE OF THE ATTORNEY GENERAL

ST. PAUL 55155

ADDRESS REPLY TO:
ATTORNEY GENERAL'S OFFICE
POLLUTION CONTROL DIVISION
1935 WEST COUNTY ROAD B-2
ROSEVILLE, MN 55113
TELEPHONE: (612) 296-7342

July 6, 1983

David Hird
U.S. Dept. of Justice
Environmental Enforcement Section
Land & Natural Resources Division
Room 1230
Washington, D.C. 20530

Re: U.S. v. Reilly Tar & Chemical Corp.
File No. Civ. 4-80-469

Dear David:

Enclosed is a copy of a memo from Dr. Andrew Dean, State Epidemiologist, commenting on the proposal by Herman Gibb for further epidemiological study in St. Louis Park. I have not enclosed attachments to Dr. Dean's memo since they are either items you already have or are summarized in the memo.

Very truly yours,

Steve Shakman

STEPHEN SHAKMAN
Special Assistant
Attorney General

SS:jh
enclosure
cc. Robert E. Leininger, EPA
Michael Hansel, PCA
Paul Zerby, AG/MDH
Dennis Coyne, AG/PCA

TO : Herman Gibb **DATE:** June 29, 1983

FROM : Andrew G. Dean, M.D., M.P.H., Director **PHONE:** 623-5363
Div. of Disease Prevention and Control

SUBJECT: Comments on "Proposal for a Breast Cancer Case-Control Study in St. Louis Park, Minnesota."

I am grateful for the opportunity to comment on the proposal, an earlier version of which Jack Mandel had shared with me. Before offering specific comments on the protocol, I would like to clarify several points about the need for studies and effective ways of carrying out a study and making use of the results.

First of all, although you may have sensed a certain lack of enthusiasm on my part for particular study proposals, my enthusiasm is directly related to the scientific validity of the study proposal, and to its overall value for the health--both mental and physical--of the people of St. Louis Park. The field of environmental epidemiology has had quite enough poorly designed and poorly communicated studies with resultant public and scientific confusion, and I believe you would agree that no study is better than one of dubious validity.

Second, there certainly is a scientific need for further studies in St. Louis Park, if these can further explore the association or lack of association between PAH in drinking water and the incidence of cancer or other effects. From a state and local perspective, however, the effects of the pre-1978 St. Louis Park water supply are of historical and scientific interest, but would not apply to the present situation, in which, I am told, levels of PAH are monitored and maintained at or below levels considered acceptable. From a national perspective, obviously the results of a valid study would provide guidance for handling similar situations in other states, and I quite understand your own and E.P.A's interest in funding and mounting further studies. We, too, feel it is appropriate for EPA to provide funds for such work; in fact, we applied to EPA for funding several years go, which was turned down. Whatever the auspices, however, we feel that a well-designed study of cancer in St. Louis Park, particularly since 1971 when the TNCS terminated, would be most valuable, and we would do our part to assist in carrying out such a study.

Careful thought must be given to the means of carrying out a study in the community setting and of communicating both its purpose and its results to the community. I personally don't feel that either ethics or practicality allows it to be done as a "general survey of health" although this would be far better from the epidemiologic point of view. It seems to me that a study officially funded by the EPA would receive wide public attention from the beginning and that plans should be made to handle public communication in the most professional and effective way possible. Provision for this activity in advance may avert misconceptions which can arise from even the best of scientific studies. I

would hope that planning for effective communication with the press, community leaders and the public would be built into the plan for the study.

The protocol you provided has been reviewed by Alan Bender, Chief of Chronic Disease Eppidemiology, by Michael Sprafka in his section and by Michael Convery in the Division of Environmental Health Services. Their comments are attached. I believe their remarks emphasize sufficiently that single 1978 water assays from particular wells are not a measure of exposure to PAH upon which a valid study can be based. Neither this method nor the other two methods of choosing an "exposed" population can be verified and they seem to represent little more than a shot in the dark.

The proposal as written cites the paper in which we described elevated rates of breast cancer and possibly GI cancer in women in St. Louis Park, based on TNCS records. I believe that the subsequent more detailed study of breast cancer cases in St. Louis Park and their compeers in the surrounding Metro area should also have been discussed. Although the study has not yet been published in a refereed journal, the conclusions were given in a copy of the Disease Control Newsletter and in our private discussions during your visit. The statistical methods are not easy to understand, but they have been reviewed by several good epidemiologists including Jack Mandel and Leonard Schuman. I believe they agree with the main conclusion that the most likely explanation for the difference in breast cancer rates between St. Louis Park and the rest of the Metro area is a difference in the pattern of other well-established risk factors for breast cancer in the two communities, and that there is little or no need to invoke PAH in water as an additional risk factor to explain the TNCS findings.

Enclosed are copies of the Newsletter article and a draft manuscript which further describes the study. I would welcome your comments or those of your colleagues on the manuscript. We hope to recalculate the expected ratio of breast cancer incidence in St. Louis Park to breast cancer incidence in the Metro area using odds ratios derived from a study that employed multivariate analysis before submitting the manuscript for publication. I think this study provides reasonable evidence against a unique connection of breast cancer and PAH in St. Louis Park (during 1969-71), and I would very much support Mike Sprafka's desire to see the study look at several common cancers and not merely at breast cancer. It is likely that doing so would not add a large proportion to the cost of the study, once preparations have been made and a research team placed in the field.

Concerning study design, I don't feel that the design based on arbitrary assumption of exposure being connected with proximity to positive water sample results in 1978 is adequate basis for the entire study. For practical reasons, the case-control design seems the best (or only) choice.

I would suggest that several parameters be used to represent "exposure", including length of residence in St. Louis Park, private well vs. city well exposure (as determined from billing records), hours spent at home, etc. Is there any possibility that the walls of water pipes or their encrusted surfaces would offer a chance for chemical measurement of cumulative PAH content in the water passing through? Perhaps you can find a chemist who is intrigued with this question. There may be other components of creosote that could serve as a proxy measurement of past exposure if these accumulate in the walls of pipes.

Selecting the controls is central to the whole project. Since geographic location will be one of the outcome variables, it is important that the method of identifying controls not produce a neighborhood match or a non-random distribution geographically. For that reason I would not use the Waxberg random dialing procedure, which results in clusters of numbers. Such clustering could have uncertain biasing effects not only on geographic location but also on length of residence. The Waxberg technique was designed as a compromise between true random selection and the practical difficulties in obtaining a list of telephone numbers on a national scale. St. Louis Park, however, has a telephone book and I believe, a street directory, and names, addresses or telephone numbers can be pulled randomly from the pages of one of these sources in order to reach a control population. In the case of the telephone book, one can substitute two random digits for the last two digits to reach unlisted numbers. Close attention would have to be paid to size of "household" (number of people on a phone number), since if many of the cases are in large institutions (e.g. nusing homes), the likelihood of reaching comparable sized institutions through random telephone numbers is smaller than it should be (the risk of being contacted is proportional to the number of telephone lines, not number of inhabitants). I think you will have an easier time examining this and similar effects in a simple random selection process rather than the Waxberg technique, but the problems of bias in control selection, whatever the method, are far from trivial.

You state in the protocol that the Minnesota Department of Health will provide access to hospital records. This is indeed a possibility, provided the final protocol is acceptable and that a collaborative working agreement or contract is signed--probably by the Commissioner. The law governing acess to records is useful mainly in removing liability from hospitals who voluntarily agree to particicpate, and we very rarely operate in the draconian manner which some might infer from your description of the process. I believe it is fair to say that the possibilities of obtaining cooperation and access to records are excellent with appropriate efforts at communication and with a study design supported by ourselves, CDC and the Department of Epidemiology (Jack Mandel). We would do everything possible to assist in this part of the process, although appropriate resources should be made available through the grant if large time commitments are involved.

In summary then, I consider several points important:

1. The work done subsequent to Dusich et al.'s article points to factors other than PAH in the water as an explanation of high breast cancer rates in St. Louis Park. Further work, therefore, should not be focused on breast cancer alone.

2. The Division of Disease Prevention and Control would be glad to participate in a well-designed study, if sufficient resources are available, and particularly if Jack Mandel is participating. A final agreement, however, would require our review of the completed protocol and review by the Commissioner of Health.

3. A satisfactory plan for the study would need to address not only the scientific aspects but the methods of communicating results to the public.

4. The role of confounding risk factors for various types of cancer needs to be addressed in the protocol and questionnaire.

5. Additional thought needs to be given to adequate measures of exposure to PAH in the water, as this is a very uncertain area.

I am sure this seems to offer a large number of objections and very little enlightenment. Nevertheless, I believe a reasonably good study is possible. Whether performing such a study for historical and scientific reasons is worth the investment in comparison with cleaning up the problem is of course something which the funding agency must decide. If they decide affirmatively, I look forward to working with you to accomplish a study of the highest possible quality.

:lmb
cc: Jack Mandel, Dept. of Epidemiology,1 University of MN
Lee Thomas, EPA
Gene Lucero, EPA
Dr. James Ruttenber, CDC
Dr. Frank Lisella, CDC
Sister Mary Madonna Ashton, Commissioner of Health
Dr. Valentine O'Malley, Deputy Commissioner
David Giese, Environmental Health
Michael Convery, Environmental Health
Stephen Shackman, Attorney General's Office